K071401

Special 510k Submission
X3C 2200 Digital Radiographic System

510k Summary

JUN 22 2007

1. **Submitter:** Imaging Dynamics Company Ltd
Suite 151, Pegasus Way NE
Calgary, AB,
Canada T2E 8M5

   Contact person: Shirantha Samarappuli
Manager – Regulatory Affairs
Tel: 403 251 9939; Fax: 403 251 1771

   Date Prepared: May 14, 2007

2. **Device Name:** X3C 2200 Digital Radiographic System,

3. **Device Classification:** Class II, 892.1680 (KPR), 892.1630 (MQB),

4. **Predicate Device:** Xplorer 2200 Digital Radiographic System (K063039)

5. **Device Description:** The X3C 2200 is a modification to Xplorer 2200 where the Xplorer 1000 digital radiographic detector (a previously marketed device covered by 510k K992955) in Xplorer 2200 system is replaced with X3C digital radiographic detector, previously marketed device under K070079. The X3C 2200 system is manufactured by Imaging Dynamics.

6. **Indications for Use:** The X3C 2200 is intended for use by a qualified/trained doctor or technologist on both adult and pediatric patients for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts on both adult and pediatric patients. Applications can be performed with patient sitting, standing or lying in the prone or supine positions. The X3C 2200 (510k submission device) is not intended for mammography.

7. **Comparison with predicate device:** The X3C 2200 is substantially equivalent to the currently marketed Xplorer 2200. X3C 2200 device does not alter the fundamental scientific technology from Xplorer 2200 predicate device. The replacement of Xplorer 100 digital radiographic detector (K992955) with X3C digital radiographic detector (K070079) is the only significant change between the 2 devices. X3C 2200 has the same intended use as the predicate device.

   a. Non-clinical tests: The device has been evaluated for performance, biocompatibility and effectiveness as well as thermal, electrical and mechanical safety and has been found to substantially equivalent to predicate device. The design and development process of the manufacturer conforms to 21 CFR part 820, ISO 9001 and ISO 13485 quality systems.
   b. Clinical tests: No clinical tests conducted.
   c. Conclusion: The device was evaluated against the predicate device (Xplorer 2200 – K063039) for all performance, safety & effectiveness requirements and found as substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Ms. Shirantha Samarappuli
Manager – Regulatory Affairs
Imaging Dynamics Company Ltd
151, 2340 Pegasus Way NE
Calgary, Alberta, T2E 8M5
CANADA

JUN 22 2007

Re: K071401
Trade/Device Name: X3C 2200 Digital Radiographic System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR, MQB
Dated: May 18, 2007
Received: May 21, 2007

Dear Ms. Samarappuli:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Special 510k Submission
X3C 2200 Digital Radiographic System

Indications for Use

510(k) Number (if known): _____

Device Name: X3C 2200 digital radiographic system

Indications for Use:

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The X3C 2200 (510k submission device) is not intended for mammography.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K071401

Prescription Use ✓ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)